In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-1841V
Filed: November 13, 2023

KATHY STILLER,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for petitioner.
Rachelle Bishop, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On December 14, 2020, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that she suffered the Table Injury of Shoulder Injury Related to Vaccine Administration ("SIRVA") in her right shoulder following tetanus diphtheria and acellular pertussis ("TDaP") vaccination that she received on October 11, 2019. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is entitled to compensation for her alleged Table Injury.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10, *et seq.*

general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. § 300aa-11(c). Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination, which is also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. *See* § 300aa-13(a)(1); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a).

As relevant here, the Vaccine Injury Table lists a SIRVA as a compensable injury if it occurs within 48 hours of vaccine administration. *See* § 300aa-14(a), *amended by* 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that her injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR § 100.3(c)(10).

Vaccine Program petitioners must establish their claim by a "preponderance of the evidence." § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). However, a petitioner may not receive a Vaccine Program award based solely on her assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. *See* § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005) (citation omitted); § 300aa-13(a)(1)(B).

II. Procedural History

This case was initially assigned to the Special Processing Unit ("SPU") on August 21, 2020. (ECF Nos. 10-11.) Petitioner filed her medical records and an affidavit in December of 2020 and January of 2021. (ECF Nos. 1, 8; Exs. 1-6.) She subsequently filed a supplemental affidavit marked as Exhibit 7. (ECF No. 20.) While the case was in the SPU, the parties attempted settlement, but were unable to resolve the case. (ECF No. 28.) Respondent filed his Rule 4 Report on August 1, 2022. (ECF No. 30.) Respondent primarily challenged petitioner's Table Injury claim of SIRVA on the basis that she had preexisting right shoulder pathology and that her condition was not limited to her right shoulder (*i.e*. SIRVA QAI criteria (i) and (iii)). (*Id.* at 6-10.) He also indicated that an alternative cause-in-fact claim was unsupported. (*Id*. at 9-13.) Thereafter, petitioner filed updated orthopedic medical records. (ECF No. 31; Ex. 8.)

While the case was still within the SPU, petitioner filed a motion for a ruling on the record, arguing she should be found entitled to compensation for a Table SIRVA. (ECF No. 33.) Respondent responded on November 16, 2022.[3] (ECF No. 34.) Respondent raised no objection to resolving entitlement on the existing record, but urged that the case be dismissed. (*Id.*) The case was subsequently reassigned to the undersigned on October 5, 2023, with petitioner's motion pending. (ECF Nos. 35-36.) On October 10, 2023, petitioner filed a joint status report on behalf of the parties confirming that the parties continue to believe the case is ripe for a ruling on petitioner's motion. (ECF No. 37.)

In light of the above, I have determined that the parties have had a full and fair opportunity to present their cases and that, given the parties' assent, it is appropriate to resolve entitlement on the existing record. *See* Vaccine Rule 8(d); Vaccine Rule

[3] In his brief, respondent provides links to two online sources regarding os acomiale and impingement syndrome respectively. (ECF No. 34, n. 4-5 (citing Thomas Youm et al., *Os Acromiale: Evaluation and Treatment*, 8 AM. J. ORTHOPEDICS 382 (2005); A. E. Fongemie, D. D. Buss, & S. J. Rolnick, *Management of Shoulder Impingement Syndrome and Rotator Cuff Tears,* 57 AM. ACAD. FAM. PHYSICIANS 667 (1998)).) These links provide only the abstracts of the cited articles. I have reviewed the abstracts available by following the links provided; however, respondent's link citations are inadequate to place the entirety of the cited articles into evidence.

3(b)(2); *see also Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record"). Accordingly, this matter is now ripe for resolution.

III. Factual History

a. As Reflected in the Medical Records

i. Pre-vaccination

Petitioner's prior medical history is not informative of the issues presented by the parties except that respondent notes that petitioner had a history of treatment for neck and mid-back pain in February of 2017. (ECF No. 34, p. 2.)

Specifically, on February 7, 2017, petitioner presented for care for neck and mid-back pain. (Ex. 2, p. 24.) She reported a prior history of neck pain associated with temporomandibular joint disorder ("TMJ") that had improved until she reinjured her neck during a falling incident with her dog. (*Id*.) Her neck pain did not radiate, and she did not have tingling, numbness, or weakness. (*Id*.) On exam, she had limited flexion, extension, and rotation of the neck and bilateral tenderness of the trapezius with spasms. (*Id.*) No separate shoulder exam was performed. (*Id*. at 24-25.) She was diagnosed in relevant part with cervicalgia for which she was started on ibuprofen and baclofen. (*Id.* at 25.) A physical therapy evaluation was also recommended. (*Id*. at 25.)

Petitioner subsequently sought follow up care for the same complaints at the emergency department on February 12, 2017. (Ex. 5, p. 5.) Examination of the neck indicated no tenderness, but mildly limited range of motion. (*Id*. at 9.) Again, no separate shoulder exam was documented. (*Id*.) A cervical spinal x-ray was unremarkable. (*Id*. at 27.) She was diagnosed with a right paracervical muscle spasm and prescribed Naprosyn, Robaxin, and Medrol. (*Id.* at 8, 12.)

At her next annual physical on January 22, 2018, it is noted that petitioner was taking baclofen "rarely" for neck pains she attributed to her TMJ. (Ex. 2, p. 19.) Petitioner explained that by taking the baclofen only as she needed, her prescription had lasted a full year; however, she requested a refill. (*Id.*) No pertinent physical findings were documented and cervicalgia was not included in her diagnoses at this encounter, though her baclofen was refilled for neck pain associated with her TMJ. (*Id*. at 21-22.)

Petitioner returned to her primary care physician for another complete exam on October 11, 2019. (Ex. 2, p. 13.) It is again noted that petitioner rarely uses baclofen for neck pain associated with her TMJ. (*Id*. at 14, 15.) At this encounter petitioner was administered an Adacel TDaP vaccination in her right deltoid, which is the vaccination at issue in this case. (*Id*. at 15; *see also* Ex. 1.)

ii. Post-vaccination

Two weeks after vaccination, on October 25, 2019, petitioner returned to her primary care provider with a specific complaint of "joint pain following adacel." (Ex. 2, p. 11.) The history of present illness specifies that onset occurred "that night" after the vaccination, but with improvement thereafter. (*Id*.) Petitioner complained of "pain in bil[ateral] upper arms, worse in the right arm where she received the shot. Lift her arms up or trying to put a bra on is painful. Feels weaker when lifting things up." (*Id*.) She denied any numbness or tingling and also denied back pain. (*Id.*) She had joint stiffness, but normal range of motion in her arms. (*Id*.) Physical exam confirmed normal range of motion in her cervical spine as well as "full ROM of shoulder and elbow in all directions even though pt states that she has pain w/ mvmt." (*Id*. at 12.) Petitioner was diagnosed with "pain in the right arm" and started on a Medrol dosepak. (*Id.*) Her physician suspected her symptoms were due to her TDaP vaccination given that they started the night of the vaccination. (*Id*.)

On November 14, 2019, petitioner followed up with an orthopedic specialist where she was seen by a physician's assistant ("orthopedic PA"). (Ex. 3, p. 60.) This time, she presented specifically for evaluation of her right shoulder for pain that she reported started "immediately" after her TDaP vaccination. (*Id*. at 60-61.) Petitioner reported that she also initially felt some pain in her left shoulder and legs. (*Id*. at 61.) She denied any problem with her right shoulder prior to vaccination. (*Id.*) She noted slight soreness in her neck, but denied any paresthesia down the arm. (*Id.*) Her cervical spinal examination was normal with no reproduction of shoulder symptoms with range of motion. (*Id*.) Examination of her right shoulder revealed no significant tenderness of the shoulder, but did produce limited and painful range of motion with internal rotation. (*Id.*) She had positive impingement and rotator cuff pain and weakness. (*Id.*) Left shoulder exam revealed no abnormalities, with full and not painful range of motion. (*Id.*) An x-ray of the right shoulder revealed "[o]s acromiale[4] with degenerative changes. Otherwise normal." (*Id*. at 64.) An MRI was recommended to rule out a rotator cuff tear. (*Id.* at 60.) The orthopedic PA opined, "I do not feel as if the vaccination caused this issue but may have exacerbated a pre-existing issue that was asymptomatic prior to the injection."[5] (*Id.*) During this encounter petitioner also sought an evaluation for left knee pain she was experiencing during workouts. (*Id.*) Petitioner subjectively felt the pain had increased post-vaccination, but her orthopedist advised

[4] The "os acromiale" is "a movable joint between the spine of the scapula and the epiphysis of the acromion." *Os acromiale,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=95081&searchterm=os+acromiale (last visited Nov. 7, 2023). As respondent explains, it is an anatomical variant. (ECF No. 34, pp. 11-12, n. 4.) It is often discovered only incidentally, but when symptomatic can present similarly to subacromial impingement syndrome.

[5] It should be noted that this opinion is not actually inconsistent with a Table SIRVA. Several prior decisions have explained that Table SIRVA encompasses asymptomatic shoulder pathology activated by vaccination. *Grossmann v. Sec'y of Health & Human Servs*., No.18-13V, 2022 WL 779666, at *16-18 (Fed. Cl. Spec. Mstr. Feb. 15, 2022); *Lang v. Sec'y of Health & Human Servs*., No. 17-995V, 2020 WL 7873272, at *12-14 (Fed. Cl. Spec. Mstr. Dec. 11, 2020); *Gurney v. Sec'y of Health & Human Servs*., No. 17-481V, 2019 WL 2865490, at *5-8 (Fed. Cl. Spec. Mstr. Apr. 24, 2019).

her knee pain was unrelated. (*Id.* at 60-61.) Regarding her right shoulder, petitioner was diagnosed with "[w]orsening right shoulder pain following tetanus vaccination; probable rotator cuff strain in the setting of AC joint degenerative changes and os acromiale." (*Id*. at 60.)

An MRI of petitioner's right shoulder was completed on November 23, 2019. (Ex. 2, p. 79.) The MRI revealed the following: (1) moderate tendinosis of the supraspinatus and infraspinatus with generalized partial thickness tearing and fraying; (2) insertional subscapularis tendinosis with partial thickness tearing; (3) an intact biceps tendon; (4) fraying of the posterior superior labrum; (5) moderate degenerative changes in the acromioclavicular joint, with a type II acromion,[6] moderate inflammatory changes, unfused acromial apophysis, and os acromiale with edema at the synchondrosis; and (6) subacromial/subdeltoid bursitis with moderate glenohumeral effusion. (*Id*. at 80.)

Following the MRI, petitioner followed up with the orthopedist on December 2, 2019. (Ex. 3, p. 47.) The orthopedist noted petitioner's initial evaluation with the orthopedic PA but did not otherwise revisit the history of onset or underlying cause of petitioner's complaints. (*Id*.) On physical exam, petitioner did not have tenderness to palpation except over the AC joint. She had reduced range of motion, signs of impingement, and rotator cuff weakness. (*Id*. at 47-48.) The orthopedist interpreted the MRI as revealing "evidence of significant inflammation at the os acromiale and bursitis. There is rotator cuff tendinosis. No clear evidence for fracture or rotator cuff tears otherwise." (*Id*. at 48.) Petitioner was diagnosed with both a symptomatic os acromiale with impingement as well as bursitis. (*Id*. at 47.) Physical therapy was recommended. (*Id*. at 48.)

Petitioner had a physical therapy evaluation on June 1, 2020. (Ex. 3, p. 41.)[7] Her chief complaints were "right shoulder loss of movement, loss of strength, pain, stiffness and tenderness." (*Id*.) She reported worsening pain following her October 2019 tetanus vaccination along with significant loss of range of motion. (*Id.*) She also "mention[ed] she had similar pain in left shoulder as well as leg pain/tightness." (*Id*.) She "hop[ed] to return to light weights/fitness which she is currently unable to do." (*Id*.) Upon exam, petitioner had tenderness in both shoulders, but only tested positive for impingement in her right shoulder. (*Id*. at 41-43.) She had similarly reduced range of motion in both shoulders, worse on the right. (*Id*. at 42.)

Petitioner attended nine physical therapy sessions between June and September of 2020. (Ex. 3, pp. 14-40.) Respondent suggests the physical therapy included both shoulders (ECF No. 30, p. 5); however, the record is ambiguous. Although petitioner's left shoulder was evaluated, her documented plan of care only ever included her right

[6] The "acromion" is "the later extension of the spine of the scapula, projecting over the shoulder joint and forming the highest point of the shoulder." *Acromion,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=708&searchterm=acromion (last visited Nov. 7, 2023). Respondent explains that a "Type II acromion" is an anatomic variant that increases the risk of rotator cuff impingement and tears. (ECF No. 34, p. 12, n. 5.)

[7] The record is silent as to the reason for the six month gap in treatment.

shoulder. (Ex. 3, pp. 14-40.) In the midst of her physical therapy for her shoulder, petitioner paused her care to pursue further treatment for her left knee. (Ex. 3, pp. 5-13, 35, 44-46; Ex. 2, p. 32-33.)

Petitioner returned to her primary care provider on October 16, 2020, for her annual exam. (Ex. 2, p. 6.) Regarding her shoulder, petitioner reported that "[s]he had pains in arm afterwards that persists even into today. Says her arm 'sticks' & she can't do Boot camp anymore, frustrated. Saw 2 docs at UB Ortho but wasnt [*sic*.] happy & doesnt [*sic*.] want to go back. Still doing PT." (*Id.*) A further note specifics that petitioner "did not have previous injury to that shoulder, had been active in BOOT camp at the time, now still unable to participate in class & frustrated." (*Id*. at 9.) Petitioner was prescribed a topical gel. (*Id*.)

Subsequently petitioner sought a second orthopedic opinion on November 9, 2020. (Ex. 6, p. 5.) She reported that "her symptoms began in 2019 after receiving a tetanus vaccine, recently worsening with weight lifting exercises." (*Id*.) "The pain is continuous and described as sharp. The pain is located on the upper arm. The pain is worse with activity, exercises including burpies, driving, raising the arm upwards. Anti-inflammatories helps alleviate the pain. Associating symptoms include weakness and shooting pain, pain at night." (*Id*.) Exam of the cervical spine showed normal range of motion. (*Id*. at 6.) She had mild tenderness over right the acromioclavicular joint, biceps, and lateral rotator cuff insertion as well as positive Hawkins and Neers tests. (*Id*.) The orthopedist also reviewed the prior MRI, concluding it showed diffuse degenerative changes without obvious rotator cuff tearing. (*Id.*) He diagnosed impingement syndrome, bursitis, and a superior glenoid labrum lesion. (*Id.*) Petitioner received a subacromial cortisone injection. (*Id*. at 7.)

Petitioner returned to the same orthopedist for a follow up on December 14, 2020. (Ex. 6, p. 8.) She reported that "[s]he has been trying to do exercises including planks." (*Id*.) The prior subacromial cortisone injection "provided relief although symptoms persist at a lower intensity." (*Id*. at 9.) Additional treatment options, including repeat cortisone injections and surgery, were discussed as well as "the demands of planks/push ups/shoulder presses and recommended modification." (*Id*.) Petitioner received a second cortisone injection on January 25, 2021. (Ex. 8, p. 2.) She was also continuing to do home exercises. (*Id*.) She was instructed to continue her home exercises and to follow up on an as needed basis. (*Id*. at 3.) No further medical records were filed.

b. As Reflected in Petitioner's Affidavit

Petitioner filed two affidavits in this case. (Exs. 4, 7.) In her first affidavit petitioner describes developing "severe deep pain in my right shoulder" on the day of her October 11, 2019 TDaP vaccination. (Ex. 4, ¶ 4.) In her second affidavit, she further specifies that as of the night of the vaccination "I started to feel pain in my right upper arm where I received the injection. In the days thereafter, the pain continued to increase and I lost my range of motion." (Ex. 7, ¶ 3.)

In her second affidavit, petitioner explains that she was "fit and healthy" prior to her vaccination and that she "had been going to bootcamp classes for three (3) years." (Ex. 7, ¶ 4.) She indicates that since the vaccination she has not been able to return to the bootcamp classes. (*Id*. at ¶ 5.)

In both affidavits, petitioner indicates that she has ongoing limitations. In the first affidavit she indicates that "I continue to experience pain, weakness, and limited range of motion in my right shoulder." (Ex. 4, ¶ 7.) In the second affidavit she states that "[t]wo (2) years later I am still unable to use my arm at the same level I was using it prior to receiving the TDaP vaccination and probably never will be." (Ex. 7, ¶ 6.)

IV. Discussion

Petitioner argues that she has satisfied all four of the QAI criteria for demonstrating that her right shoulder injury constitutes a Table SIRVA and that she should be found entitled to compensation for that Table injury. (ECF No. 33.) Respondent argues, however, that petitioner's history reflects both frequent exercise injuries and anatomic shoulder variants that predisposed her to shoulder injury. (ECF No. 34.) He contends petitioner cannot meet either the first or third SIRVA criteria because her condition is not limited to her right shoulder and, in any event, is due to preexisting shoulder dysfunction. (*Id*.)

Because of the nature of respondent's arguments, discussion of petitioner's alleged Table injury is best facilitated by taking the four SIRVA criteria out of order. Timing of onset under the second SIRVA criterion is addressed first. Next, analysis of the third SIRVA criterion addresses respondent's contention that petitioner's medical history demonstrates that petitioner's symptoms are best viewed as part of a pattern of injuries and are, therefore, not confined to her shoulder. Finally, the first and fourth criteria are examined together to address respondent's contention that petitioner's condition is ultimately explained by preexisting shoulder dysfunction.

For the reasons discussed below, I conclude that petitioner has met her *prima facie* burden of proof with respect to each of the four QAI criteria for establishing a Table Injury of SIRVA. I further conclude that respondent has not met his burden of proof with respect to whether petitioner's condition was caused by any factor unrelated to vaccination. Accordingly, petitioner is entitled to compensation for a Table SIRVA.

a. Petitioner's *Prima Facie* Showing of a Table SIRVA

i. Pain occurs within 48 hours of vaccination (second criterion)

As an initial matter, the fact that the timing of petitioner's shoulder pain supports a Table SIRVA is not meaningfully disputed. The second SIRVA criterion requires that the "[p]ain occurs within the specified time-frame," *i.e.*, within 48 hours of vaccination.

42 CFR § 100.3(c)(10)(ii); 42 CFR § 100.3(a). Petitioner explains in her motion that her medical records establish the onset of her shoulder pain was the same day as her vaccination. (ECF No. 33, p. 8 (citing Ex. 2, p. 11; Ex. 3, p. 62; Ex. 7, ¶ 3).) I agree. Respondent has not raised any specific argument to the contrary. (ECF No. 34.) Thus, petitioner has satisfied the second SIRVA criterion by preponderant evidence.

ii. Pain and reduced range of motion are limited to the affected shoulder (third criterion)

The third SIRVA criterion requires that for a shoulder injury to constitute SIRVA the "[p]ain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered." 42 CFR § 100.3(c)(10)(iii). Despite the fact that petitioner suffered onset of right shoulder pain post-vaccination, respondent places her shoulder pain in a broader context of pain complaints that he asserts is incompatible with this SIRVA requirement. (ECF No. 34, pp. 8-10.) This is not persuasive.

Respondent argues that petitioner "consistently reported pain outside her vaccinated shoulder." (ECF No. 34, p. 8.) In particular, he notes that at her first post-vaccination encounter with her primary care provider petitioner reported bilateral shoulder pain. (*Id*. at 9 (citing Ex. 2, p. 11).) He further notes that petitioner subsequently complained of neck and knee pain to the orthopedist. (*Id*. (citing Ex. 2, p. 40).) Later, when petitioner presented for physical therapy, she again complained of bilateral shoulder pain as well as knee pain. (*Id.*) At that time reduced range of motion in the left shoulder was confirmed. (*Id*. (citing Ex. 3, p. 41-42).) Thus, respondent argues that "[e]ven if petitioner's right shoulder injury were characterized as the focus of her complaints and treatment, petitioner's condition cannot be said to be "localized to the shoulder in which the vaccine was administered." (*Id*. at 10 (quoting 82 Fed. Reg. 6294-01).) Petitioner argues, however, that "there is no evidence of an injury extending beyond petitioner's right shoulder. While the record contains stray notations of pain in other parts of petitioner's body (i.e. pain in both arms and soreness in her legs), petitioner's injury is consistent with the definition of SIRVA and there is not preponderant evidence of another etiology." (ECF No. 33, p. 8.)

In interpreting the third SIRVA criterion, both parties cite the undersigned's prior decision in *Grossman v. Secretary of Health and Human Services* for the proposition that "[i]t is clear that the gravamen of this requirement is to guard against compensating claims involving patterns of pain or reduced range of motion indicative of a contributing etiology beyond the confines of a musculoskeletal injury to the affected shoulder." (ECF Nos. 33-34 (citing 2022 WL 779666, at *15).) In *Grossman*, the petitioner subjectively reported to her treating physicians that she was experiencing pain beyond the confines of her shoulder, which prompted her treaters to initially consider the possibility of a cervical etiology for her pain; however, they ultimately ruled out a cervical etiology and concluded she suffered a shoulder injury. 2022 WL 779666, at *16. Examining respondent's response to public comment for his SIRVA rulemaking revealed that he had explained that SIRVA is "a condition localized to the shoulder," thus he required pain and reduced range of motion must be limited to the affected shoulder to accurately

reflect that condition. (*Id*. at 15.) However, because the *Grossmann* petitioner's treating physicians diagnosed a shoulder injury and rejected her additional pain complaints as diagnostically useful, they did not suggest any etiology for petitioner's condition beyond the confines of a musculoskeletal injury to the shoulder. (*Id.* at 16.)

In this case, as petitioner argues, her medical records document a distinct onset of right shoulder pain and reduced range of motion occurring post-vaccination which was confirmed by orthopedic exam. (Ex. 3, pp. 47-48, 60-61.) Underlying shoulder pathology was further confirmed by MRI study. (Ex. 2, p. 79.) Ultimately, although petitioner did once reference "slight soreness into the neck" (Ex. 3, p. 61), petitioner's symptoms were diagnosed by her treating orthopedist as both impingement and bursitis of the right shoulder (Ex. 3, pp. 47-48), two conditions limited to the shoulder. *Accord Werning v. Sec'y of Health & Human Servs.,* No. 18-0267V, 2020 WL 5051154, at *10 (Fed. Cl. Spec. Mstr. July 27, 2020) (finding that a petitioner satisfied the third SIRVA QIA criterion where there was a complaint of radiating pain, but the petitioner was "diagnosed and treated solely for pain and limited range of motion to her right shoulder.")

Although respondent is correct that petitioner had other documented musculoskeletal complaints, respondent has not cited any medical opinion, whether in petitioner's own medical history or by expert analysis, to support his contention that petitioner's various complaints in other parts of her body can be unified to suggest that the pain and reduced range of motion attributable to her diagnosed right shoulder injury in itself extended beyond her affected shoulder. *Accord Rodgers v. Sec'y of Health & Human Servs.*, No.18-559V, 2021 WL 4772097, at *8 (Fed Cl. Spec. Mstr. Sept. 9, 2021) (explaining that the third SIRVA criterion "does not prevent a petitioner with simultaneous areas of pain due to unrelated conditions from also meeting the Table SIRVA definition.") In fact, respondent's contention is directly contradicted by the medical records in that petitioner was specifically advised that her knee pain was unrelated to her shoulder complaints[8] and following a cervical muscle spasm in February 2017 her primary care physician ultimately attributed her lingering neck pain to her TMJ. (*See* Ex. 2, p. 13, 19.) In any event, even if respondent were persuasive in arguing that petitioner's various musculoskeletal issues should all be categorized collectively as exercise-related injuries, they would still each constitute *separate* injuries.

Respondent stresses the bilateral nature of the initial onset of shoulder pain. (ECF No. 34, p. 9.) However, no medical opinion ties petitioner's shoulder complaints and the medical records do not establish that petitioner's left shoulder pain followed a

[8] In his motion response, respondent accurately quotes the orthopedic PA as indicating petitioner's knee symptoms "do not seem to be associated to her recent vaccination at all." (ECF No. 34, p. 11 (quoting Ex. 2, p. 39).) However, that quotation must be understood in the surrounding context. That sentence directly follows a statement accepting that petitioner's shoulder complaint may constitute a vaccine-caused exacerbation of previously asymptomatic shoulder issues. (Ex. 3, p. 60.) The same record also indicates that petitioner's knee pain began prior to vaccination and in the context of work outs, though she felt it worsened subsequent to vaccination. (*Id*. at 61.) Looking at the record as a whole, the orthopedic PA's clear opinion is that the onset of right shoulder pain may be vaccine related, but that petitioner's knee pain is a separate issue.

similar trajectory to her right shoulder pain. *Accord Montana v. Sec'y of Health & Human Servs.*, No. 20-873V, 2023 WL 7338887, at *11 (Fed. Cl. Spec. Mstr. Oct. 16, 2023) (explaining that "[a]lthough respondent is correct that some of petitioner's medical records indicate that she presented with 'bilateral' shoulder pain, the medical records do explicitly distinguish the etiology and history of the pain she experienced in each shoulder . . . [and] there is no indication from the medical records that any of petitioner's treating physicians considered her right and left shoulder pain to be a part of the same condition"). When petitioner first presented to her primary care provider, she complained of post-vaccination bilateral shoulder soreness that was already improving. (Ex. 2, p. 11.) By the time she first sought orthopedic care for her right shoulder, she reported that her initial left shoulder pain had been transient and physical examination of her left shoulder revealed no abnormality. (Ex. 3, pp. 60-61.) She did not mention left shoulder pain again until her physical therapy evaluation in June of 2020. (Ex. 3, pp. 41-43.) At that time petitioner had left shoulder deficits, but nothing in the record indicates her left shoulder symptoms were continuous. (Indeed, her prior orthopedic exam confirmed they were not.) After that, petitioner never mentioned her left shoulder pain again despite pursuing a second orthopedic opinion regarding her right shoulder.

Accordingly, petitioner has satisfied the third SIRVA criterion by preponderant evidence.

iii. <u>No history of pain, inflammation or dysfunction of the affected shoulder (first criterion) and no other condition or abnormality is present that would explain the patient's symptoms (fourth criterion)</u>

In this case, the first and fourth criteria are best addressed together. The first SIRVA criterion requires "[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection." 42 CFR § 100.3(c)(10)(i). The fourth SIRVA criterion requires that "[n]o other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy)." 42 CFR § 100.3(c)(10)(iv).

Following on from his argument with respect to the third SIRVA criterion, respondent argues that petitioner's presentation is due to anatomic and degenerative shoulder dysfunction, aggravated by her exercise routine rather than her vaccination. (ECF No. 34, pp. 11-12.) Though respondent offers this argument under the first SIRVA criterion, it also implicitly argues that another condition is present that would explain petitioner's symptoms. (*Id.*) First, respondent stresses that petitioner's orthopedist opined that "I do not feel as if the vaccination caused this issue, but [it] may have exacerbated a pre-existing issue that was asymptomatic prior to the injection." (ECF No. 34, p.10 (quoting Ex. 2, p. 39).) Second, respondent finds significance in the fact that petitioner had a high intensity workout regimen. (*Id*. at 11.) And, third, respondent argues that petitioner had anatomic issues, namely os acromiale and type II acromion, that are risk factors for rotator cuff issues. (*Id*. at 11-12.) Thus, respondent argues that

"it is petitioner's shoulder anatomy that presents as subacromial impingement syndrome and puts her at risk for rotator cuff issues, combined with her known history of frequent exercise injuries and intense exercise demands on her joints that preponderantly establishes petitioner had preexisting right shoulder pain, inflammation, or dysfunction that explains her post-vaccination condition." (*Id*. at 12.) Petitioner counters that petitioner's medical records explicitly document that she had no issues with her right shoulder prior to vaccination and that respondent's assessment fails to account for onset of shoulder pain coincident to vaccination. (ECF No. 33, pp. 6-7.)

Petitioner is clearly correct that her medical records confirm that she had no prior history of pain or inflammation of her right shoulder. In that regard, respondent misconstrues the orthopedic PA's opinion. Although the orthopedic PA expressed doubt that the vaccination alone would cause petitioner's symptoms, she confirmed any preexisting shoulder pathology would have been asymptomatic and specifically opined that any such pathology "may have been exacerbated" by petitioner's vaccination. (Ex. 2, p. 39.) Thus, contrary to what respondent argues, the orthopedic PA explicitly opined that the vaccination, not the underlying pathology, explains the presentation of signs and symptoms. *Compare, e.g., Rance v. Sec'y of Health & Human Servs*., No. 18-222V, 2023 WL 6532401, at *25 (Fed. Cl. Spec. Mstr. Sept. 11, 2023) (finding that petitioner met SIRVA QAI criterion one where he had prior episodes of shoulder pain two year prior to vaccination but "no indication that this was an ongoing shoulder issue prior to vaccination") *with French v. Sec'y of Health & Human Servs*., No. 20-0862V, 2023 WL 7128178, at *6 (Fed. Cl. Spec. Mstr. Sept. 27, 2023) (finding that a prior rotator cuff repair with sequela visible on MRI defeated a Table SIRVA under criteria one and four without necessarily being a preponderant cause).

To the extent respondent nonetheless stresses preexisting underlying dysfunction, it is true that petitioner's first orthopedist specifically diagnosed a symptomatic os acriomale. (Ex. 3, p. 47.) However, respondent's suggestion that this entirely explains petitioner's condition is not supported by any medical opinion. As has been previously observed in the context of the fourth SIRVA criterion,

> because SIRVA is by definition an unspecified "injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.)" (*see* 42 C.F.R. § 100.3(c)(10)), respondent does not defeat petitioner's claim simply by noting the presence of shoulder dysfunction beyond deltoid bursitis. Although deltoid bursitis is the specific condition that has been most clearly associated with vaccine-related shoulder injuries, the QAI definition of SIRVA was specifically drafted to encompass shoulder dysfunction beyond that condition.

Lang, 2020 WL 7873272, at *12 (citing Proposed Rulemaking, 2015 WL 4538923, at *45136). Thus, "findings consistent with impingement, rotator cuff tears, or AC arthritis do not *per se* preclude a finding that a Table SIRVA exists. Rather, the question raised by respondent's argument is whether petitioner's own clinical history

indicates that her shoulder pathology wholly explains her symptoms independent of vaccination." (*Id*. at 13.)

Here, respondent himself acknowledges that petitioner's anatomic variants were merely risk factors for rotator cuff issues. (ECF No. 34, p. 12.) In that regard, the records confirm that the orthopedic PA was already aware of petitioner's os acromiale and degenerative changes when she agreed based on clinical presentation that the symptom onset may have been due to vaccination. (Ex. 3, p. 60.) Subsequently, the orthopedist did not revisit the orthopedic PA's opinion that petitioner's shoulder pathology may have been exacerbated by vaccination. Nor following the MRI did he limit his diagnosis to impingement due to a symptomatic os acromiale. Rather, he also separately diagnosed bursitis. (*Id*.) In fact, in detecting bursitis the radiologist suspected an inflammatory etiology separate from the os acromiale. (Ex. 2, p. 80.) There is no evidence of any inflammatory process occurring prior to vaccination and, even as it is not absolutely required, subacromial bursitis is in effect a hallmark of SIRVA. 42 C.F.R. § 100.3(c)(10) (explaining that SIRVA is thought to occur "as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction.") Neither the medical records nor the article abstracts cited by respondent suggest that petitioner's os acriomiale explains her separately diagnosed bursitis.

Finally, respondent also overstates the degree to which the record implicates petitioner's exercise routine as a contributor to her right shoulder injury. (*See* ECF No. 34, p. 11.) In fact, respondent's view is entirely speculative. Petitioner's medical records support her knee injury, not her shoulder injury, as related to her exercise routine. (Ex. 3, p. 44 (petitioner "presenting now for her L knee which began bothering her approximately one year ago following a boot camp HIIT workout."); Ex. 3, p. 49 (indication for left knee MRI is "exercise related injury"). For the same reasons discussed above regarding QAI criterion three, the fact that petitioner suffered a discrete knee injury while working out is not informative of the cause of her shoulder pain. None of petitioner's medical records report any suspicion that her right shoulder injury was caused by exercise. In fact, the initial orthopedic encounter wherein petitioner reported both left knee and right shoulder pain distinguished the etiology of the two injuries. (Ex. 3, p. 60 (noting right shoulder pain to be due to vaccine-related exacerbation and left knee pain to be unrelated to vaccination). Several notations express petitioner's frustration with being unable to continue her work out routine post-vaccination. In particular, petitioner did report beginning in late 2020 that her right shoulder symptoms "recently worsen[ed] with weight lifting exercises . . . exercises including burpies, driving, raising the arms upwards." (Ex. 6, p. 5.) At that time it was further noted that petitioner "[e]xercises regularly – up until 1 year ago because of her shoulder." (*Id*.) Her second orthopedist recommended modifying her workout. (*Id.* at 9.) However, this reflects that petitioner's injury affected her exercise routine, not that her exercise routine caused her injury.

Thus, there is no evidence that petitioner had prior history of pain or inflammation of the affected shoulder. Nor is there medical evidence to suggest that either

petitioner's symptoms or the full extent of her diagnostic studies can be explained by preexisting shoulder dysfunction. Thus, based on my review of the record as a whole, I find petitioner has satisfied the first and fourth SIRVA criteria by preponderant evidence.

b. Factor Unrelated

Once petitioner has satisfied her own *prima facie* burden, respondent has the opportunity to demonstrate, also by a preponderance of the evidence, that petitioner's injury was nonetheless caused by a factor unrelated to vaccination. §300aa-13(a)(1)(B); § 300aa-13(a)(2); *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013). In this case, respondent argues that petitioner's injury does not meet the specific definition of SIRVA because a combination of anatomic shoulder variants, degenerative changes, and petitioner's high intensity exercise regimen, confound that analysis. (ECF No. 34, pp. 10-13.) However, respondent does not explicitly argue that he could himself meet an affirmative burden of proof to establish these factors actually more likely than not caused petitioner's right shoulder injury. (*See generally* ECF Nos. 30, 34.) And, indeed, no medical opinion exists on this record to support respondent's interpretation of petitioner's medical history and several of his assertions are not well supported by record evidence. (*See generally* Exs.1-6; 8.) Thus, even additionally considering respondent's arguments as endorsing factors unrelated to vaccination as the cause of petitioner's injury, those arguments would still fail for all the same reasons discussed above.

V. Conclusion

After weighing the evidence of record within the context of this program, I find by preponderant evidence that petitioner suffered a Table Injury of SIRVA resulting from her October 11, 2019 TDaP vaccination. A separate damages order will be issued.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master